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EXAMINER

BOYD, JENNIFER A

ART UNIT	PAPER NUMBER
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1771

DATE MAILED: 11/06/2002

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/805,125

Examiner

Jennifer A Boyd

Applicant(s)

JANUSSON ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 - 41 is/are pending in the application.
- 4a) Of the above claim(s) 33-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 and 36 - 41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) ✓
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1 – 32 and 36 - 41, drawn to a composite elastic material, classified in class 428, subclass 145.
 - II. Claims 33 - 35, drawn to a suction liner, classified in class 623, subclass various.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of Group I and Group II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are composite elastic material and a suction liner. The composite material structure is not the same as the suction liner. Additionally, the construction of the suction liner does not anticipate the use of the composite material.
3. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.
4. During a telephone conversation with J. Ernest Kenney on October 2, 2002 a provisional election was made with traverse to prosecute the invention of Group 1, claims 1 – 32 and 36 - 41. Affirmation of this election must be made by applicant in replying to this Office action. Claims 33 – 35 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

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5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

6. The disclosure is objected to because of the following informalities: The word "views" is misspelled on page 10, line 2. Appropriate correction is required.

7. The use of the trademarks LYCRA, EXPANCEL and VASELINE has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Abstract

8. The abstract of the disclosure is objected to because the file extension found on the middle of page 23 should be deleted. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 13, 17, 24 – 26, 29 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claim 13 states “the elasticized fabric layer on said one said of said fabric layer”. The phrase appears to worded incorrectly. The suggested replacement is “the elasticized fabric layer on said one side of said fabric layer”.

12. Claim 17 requires the elasticized fabric to be from Rx-Textile. The origin of the fabric is not found to be patentably limiting as the origin of the fabric has no bearing on the final product because it does not add to the chemistry or structure of the fabric.

13. Claim 17 contains the trademark/trade name LYCRA. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a spandex fiber and, accordingly, the identification/description is indefinite.

14. Claims 24 - 26 contain the trademark/trade name VASELINE. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph.

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See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe petroleum jelly and, accordingly, the identification/description is indefinite.

15. Claims 29 and 30 contains the trademarks/trade names CF13-2188 NuSil Technology Silicone Elastomer, Baysilone Fluid M350 silicone oil, Medical Grade type WebCo 71 Vaseline, Expancel expanded 551DE microspheres, Aloe Vera Pure Beauty oil, product 78522-04001 and MED-4950, MED-4050 or CF 15-2188. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe silicone, silicone oil, petroleum jelly, plastic microspheres, aloe vera and silicone respectively and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102/103

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16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. Claims 31 – 32 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Stockwell (US 5,359,735).

19. As to claim 31, Stockwell discloses an elasticized knit textile material coated with a cured silicone elastomer. Stockwell teaches a surface coating which is a sprayable rubber material (column 2, lines 35 – 39), preferably a silicone rubber which can vulcanize or be cured at room temperature (column 2, lines 39 – 41). A thin coating of sprayable rubber material can be applied to a substrate of a stretchable fabric such as a circular knit (column 3, lines 59 – 67). Circular knitting creates tubular objects. The knitted substrate can be made of a nylon/spandex or nylon/Lycra® material (column 9, lines 27 – 35) which is stretchable due to the polyurethane content and the construction of the fabric. Due to the sprayable nature of the rubber material and the gaps in a knitted substrate, the rubber material would penetrate the knitted substrate to form a continuous coating on one side of the knitted substrate. The coating is stretchable so it will not reduce the stretchability of a coated stretchable fabric (column 9, lines 30 – 35).

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20. As to claim 32, the coating mixture may contain other materials such as metal-coated fibers (column 3, lines 31 – 40), which act as the reinforcing fibers. The metal-coated fibers would provide additional support to the layer. Although Stockwell does not explicitly teach the claimed stiffness against elongation of the liner and lack of resistance against distension in directions traverse to the liner length, it is reasonable to presume that the reinforcement matrix provides stiffness against elongation of the liner and lack of resistance against distension in directions traverse to the liner length is inherent to Stockwell. Support for said presumption is found in the use of like materials (i.e. silicone elastomer layer embedded with a reinforcement matrix) which would result in the claimed property. The burden is upon the Applicant to prove otherwise. *In re Fitzgerald* 205 USPQ 594. In addition, the presently claimed property of stiffness against elongation of the liner and lack of resistance against distension in directions traverse to the liner length would obviously have been present once the Stockwell product is provided. Note *In re Best*, 195 USPQ at 433, footnote 4 (CCPA 1977). One would have been motivated to put the metal coated fibers in the silicone coating to reinforce and further support the already elongation resistant structure.

Claim Rejections - 35 USC § 103

21. Claims 1 – 5, 7 - 22, 27 – 28 and 33 - 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klasson et al. (US 4,923,474) in view of Stockwell (US 5,359,735) in further view of Evans et al. (US 4,463,118).

Klasson discloses a sleeve-shaped article, particularly for amputation stumps (Title). The sleeve member is substantially made up of an elastic material (Abstract) such as silicone (column 6, line 13).

As to claim 3, the sleeve has a tapered and closed distal end as shown in Figure 1.

As to claims 7 and 36, a coupling means (2) made of silicone for coupling a sleeve with a prosthesis is at the bottom portion of the sleeve (column 6, lines 10 – 20) as seen in Figure 1. It is common in the art to use cured silicone for application requiring rigid supports. The coupling means is able to connect to a pin connector to retain the sleeve in place.

As to claim 8 and 9, Klasson discloses a suction liner tapered towards the distal end wherein the circular liner with the distinct radii of curvature and longitudinal axes as shown in Figure 1.

As to claims 10 and 37, Klasson discloses an interior proximal flange area of the interior wall portion is tapered outwardly and the exterior proximal flange area of the posterior wall portion is tapered inwardly as shown in Figure 1.

As to claims 11 and 38, Klasson discloses a spherical curved inside distal wall portion of the suction liner with the distal wall portion joining the adjoining interior wall of the suction liner along a tangency and the thickness of the walls of the suction liner and the anterior wall portion are the same as shown in Figure 1.

Klasson fails to disclose that the sleeve can be made of a composite material comprising a layer of cured silicone material and hollow microspheres. Klasson fails to disclose that the sleeve can be made of a composite material additionally contains an elasticized knitted fabric

layer. Klasson fails to teach that the sleeve can be in a tubular form with two open ends with fabric on the interior side and cured silicone on the exterior side. Klasson fails to disclose that the cured silicone material can contain reinforcing fibers which provide stiffness against elongation of the liner and lack of resistance in directions traverse to the liner. Klasson fails to disclose that the sleeve has the fabric layer on the exterior side and the layer of cured silicone material on the interior side. Klasson fails to disclose that the sleeve can be made of a composite material that contains another silicone layer. Klasson fails to disclose that the knitted layer is breathable on the non-coated side and waterproof on the coated side. Klasson fails to disclose that the cured silicone layer is rectangular in shape and that the edges can be sewn together. Klasson fails to teach that the composite material has a tensile strength of 1 Pa and a 100% modulus of 5 to 30kPa. Klasson fails to disclose that the knit fabric is a jersey knit with 28 needles per 2.5 cm, comprising 87% nylon and 13% polyurethane fiber. Klasson fails to disclose that the knit fabric is a circular rib knit fabric with 220 needles per 2.5 cm in 12 cm or 264 needles per 2.5 cm in 14 cm width comprising 95% nylon and 5% polyurethane fiber. Klasson fails to disclose that the microspheres can be hollow, gas-filled bodies of flexible plastic having a density range of 0.005 g/cm³ to 1.25 g/cm³, or specifically, a density of 0.05 g/cm³. Klasson fails to disclose that the silicone elastomer composition contains 50 – 99.4% silicone elastomer, 0.5 – 45% silicone oil and 0.1 – 5% microspheres or specifically contains 77.25% silicone elastomer, 10% silicone oil and 0.75% microspheres. Klasson fails to disclose that the silicone elastomer layer has the claimed density range of 0.5 g/cm³ to 1.3g/cm³, or specifically 0.94 g/cm³, a tensile strength of 0.1 Pa, or specifically 0.5 Pa, a durometer reading of 13 – 62, or specifically 22, 100% modulus of 5kPa to 250kPa, or specifically 20 kPa, and compression set of 0 to 30, or specifically 8.

As to claim 1, Stockwell discloses a surface coating which is a sprayable rubber material which can be mixed with hollow microspheres (column 2, lines 35 – 39). The sprayable rubber material is preferably silicone rubber which can vulcanize or be cured at room temperature (column 2, lines 39 – 41). Furthermore, as to claim 1, Klasson in view of Stockwell fails to disclose the addition of the silicone oil to the silicone elastomer layer. Stockwell notes that other components may be added to the mixture (column 2, lines 45 – 50). Evans teaches a heat curable oil extended silicone elastomer (Abstract). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a silicone oil as an extending material as suggest by Evans in the surface coating of Stockwell in order to improve the processability and to optimize the properties of cured reinforced silicone elastomers (Evans, column 1, lines 24 – 34). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the surface coating with hollow microspheres of Stockwell in the sleeve-shaped article of Klasson to provide thermal insulation while being flexible and light in weight (Stockwell, column 1, lines 20 – 25) motivated by the expectation of successfully implementing the invention of Klasson.

As to claim 2, Stockwell teaches that the surface coating is applied to a substrate of a stretchable fabric such as a circular knit or a four way stretch fabric which can be a jersey fabric (column 3, lines 59 – 67). The knitted substrate can be made of a nylon/Spandex or nylon/Lycra® material which is stretchable due to the polyurethane content and the construction of the fabric. It would have been obvious to one ordinary skill in the art at the time the invention was made to attach a stretchable or elasticized fabric to one side of the silicone elastomer layer in

order to provide an aesthetically pleasing exterior which has the similar stretch characteristics to the silicone elastomer layer therefore providing additional support and dimensional stability to the sleeve.

As to claim 4, Stockwell teaches a sleeve in a tubular form with the fabric on the interior side and silicone coating on the exterior side (column 11, lines 10 – 16). Klasson in view of Stockwell and Evans does not teach that the fabric can be on the exterior side of the tubular sleeve. It would have been obvious to one having ordinary skill in the art at the time the invention was made to create a tubular sleeve of Klasson in view of Stockwell and Evans with the fabric on the exterior side of the sleeve, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. *In re Einstein*, 8 USPQ 167. In the present invention, one would have used the sleeve with the fabric on the exterior and the silicone coating on the interior, motivated by the desire to have a sleeve with the form-fitting silicone adjacent to the user's skin and the fabric on the outside for an attractive interface providing breathability and comfort. It would have been obvious to one of ordinary skill in the art at the time the invention was made to create the sleeve in a tubular form to have a sleeve with uniform strength. Typically, a material that is rectangular and made into a tubular form by a seam is weaker compared to an integrally-formed tubular sleeve.

As to claim 5, Stockwell teaches the coating mixture may contain other materials such as metal-coated fibers (column 3, lines 31 – 40). The metal-coated fibers would provide additional support to the layer. Although Klasson and Stockwell in view of Evans does not explicitly teach the claimed stiffness against elongation of the liner and lack of resistance against distension in directions traverse to the liner length, it is reasonable to presume that the reinforcement matrix

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provides stiffness against elongation of the liner and lack of resistance against distension in directions traverse to the liner length is inherent to Klasson and Stockwell in view of Evans. Support for said presumption is found in the use of like materials (i.e. silicone elastomer layer embedded with a reinforcement matrix) which would result in the claimed property. The burden is upon the Applicant to prove otherwise. *In re Fitzgerald* 205 USPQ 594. In addition, the presently claimed property of stiffness against elongation of the liner and lack of resistance against distension in directions traverse to the liner length would obviously have been present once the Klasson in view of Stockwell and Evans product is provided. Note *In re Best*, 195 USPQ at 433, footnote 4 (CCPA 1977). In the present invention, one would have presumed that the reinforcement matrix provided by Klasson and Stockwell in view of Evans would provide additional stiffness against elongation of the liner due to the additional strength provided by the metal fibers.

As to claims 12 and 39, Stockwell teaches additional layers of the sprayable rubber material may be added to the composite structure. In Figure 1, Stockwell discloses a composite material with a base fabric substrate (12) such as a knitted fabric, an adjacent layer of sprayable rubber material (14) and another adjacent layer of the sprayable rubber material containing microspheres (16). Stockwell notes that Figure 1 does contain 7 total layers coating layers, however, a greater or lesser number of alternating layers may be used in alternative embodiments depending on the desired physical characteristics (column 5, lines 23-30). Due to the sprayable nature of the rubber material and the gaps in a knitted substrate, the rubber material would penetrate the knitted substrate to form a continuous coating on one side of the knitted substrate. It would have been obvious to one of ordinary skill in the art at the time the invention was made

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to add additional layers of the sprayable rubber material in order to further support the sleeve and increase its durability and lifetime.

As to claims 13 and 40, Stockwell teaches the knitted substrate is breathable on the non-coated side and waterproof on the coated side (column 3, lines 59 – 64). The sprayable rubber coating is thin (column 8, lines 30 – 40). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a knitted substrate that is breathable on the non-coated side and waterproof on the coated side in the sleeve of Klasson and Stockwell in view of Evans in order to allow the stump to remain dry in humid conditions while allowing the skin to breathe within the sleeve.

As to claim 14, the elasticized fabric layer is rectangular in shape as shown in Figure 1 of Stockwell and the edges can be sewn together (column 11, lines 14 – 16). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use an elasticized fabric layer which is rectangular in shape and capable of being sewn together as suggested by Stockwell in the sleeve of Klasson and Stockwell in view of Evans in order to provide a commonly produced substrate which can be sewn to any diameter to provide a custom fit.

As to claims 15 and 41, although Klasson and Stockwell in view of Evans does not explicitly teach the claimed tensile strength of 1 Pa and a 100% modulus of 5 to 30kPa, it is reasonable to presume that the tensile strength of 1 Pa and a 100% modulus of 5 to 30kPa is inherent to Stockwell in view of Klasson. Support for said presumption is found in the use of like materials (i.e. same composite elastic material with a cured silicone elastomer layer interspersed with hollow microspheres and an elasticized fabric layer) which would result in the claimed property. The burden is upon the Applicant to prove otherwise. *In re Fitzgerald* 205 USPQ 495.

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In addition, the presently claimed property of the tensile strength of 1 Pa and a 100% modulus of 5 to 30kPa would obviously have been present once the Stockwell product is provided. Note *In re Best*, 195 USPQ at 433, footnote 4 (CCPA 1977). In the present invention, one would have been motivated to optimize the tensile strength and modulus to assure a strong and dimensionally stable sleeve.

As to claim 16, Klasson and Stockwell in view of Evans discloses the claimed invention except for knit fabric parameters such as the number of needles per cm and the fiber composition. It should be noted that the number of needles and percent composition of nylon and polyurethane fiber are result effective variables. For example, increasing the number of needles per 2.5 cm would create a tighter and stronger knit and increasing the amount of polyurethane fiber would increase the stretchability of the fabric. It would have been obvious to one having ordinary skill in the art at the time the invention was made to create a jersey knit fabric with 28 needles per 2.5 cm comprising 87% nylon and 13% polyurethane fiber, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). In the present invention, one would have been motivated to optimize the number of needles and percent composition of nylon and polyurethane fiber to create the appropriate strength and stretch for the sleeve motivated by the expectation to successfully practice the invention of Klasson and Stockwell in view of Evans.

As to claim 17, Klasson and Stockwell in view of Evans discloses the claimed invention except for the knit fabric parameters such as the number of needles per centimeter and fiber composition. It should be noted that the number of needles and percent composition of nylon and polyurethane fiber are result effective variables. For example, increasing the number of needles

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would create a tighter and stronger knit and increasing the amount of polyurethane fiber would increase the stretchability of the fabric. It would have been obvious to one having ordinary skill in the art at the time the invention was made to create a circular knit fabric with 220 needles per 2.5 cm in 12 cm or 264 needles per 2.5 cm in 14 cm width comprising 95% nylon and 5% polyurethane fiber, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). In the present invention, one would have been motivated to optimize the number of needles and percent composition of nylon and polyurethane fiber to create the appropriate strength and stretch for the sleeve motivated by the expectation to successfully practice the invention of Klasson and Stockwell in view of Evans.

As to claim 18, Stockwell discloses the microspheres can be hollow, gas-filled bodies of flexible plastic (column 3, lines 4 – 10). Stockwell teaches that the layers can be cured at once (column 8, lines 62 – 65). During the curing process, the increased temperature would cause the microspheres to expand. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use hollow, expanded, gas-filled microspheres as suggested by Stockwell in the sleeve of Klasson and Stockwell in view of Evans motivated by the desire for cushioning the sleeve and providing a comfortable fit for the stump.

As to claims 19 and 20, Klasson and Stockwell in view of Evans discloses the claimed invention except for the use of microspheres having a density range of 0.005 g/cm^3 to 1.25 g/cm^3 as required by claim 19, or specifically, a density of 0.05 g/cm^3 as required by claim 20. It should be noted that increasing or decreasing the density of the microspheres is a result effective variable. It would have been obvious to one having ordinary skill in the art at the time the

invention was made to use microspheres having a density range of 0.005 g/cm^3 to 1.25 g/cm^3 as required by claim 19, or specifically, a density of 0.05 g/cm^3 as required by claim 20, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). In the present invention, it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the cushioning and strength of the microspheres which provide support to the sleeve structure.

As to claims 21 and 22, Klasson and Stockwell in view of Evans discloses the claimed invention except for the silicone elastomer composition containing 50 – 99.4% silicone elastomer, 0.5 – 45% silicone oil and 0.1 – 5% microspheres as required by claim 21 or specifically containing 77.25% silicone elastomer, 10% silicone oil and 0.75% microspheres as required by claim 22. It should be noted that increasing or decreasing the amount of silicone elastomer, silicone oil and microspheres are result effective variables. For example, increasing the amount of silicone would provide more elasticity to the structure, increasing the amount of silicone oil would enhance the processability of the material and increasing the amount of microspheres would increase the amount of cushioning provided. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a silicone elastomer composition containing 50 – 99.4% silicone elastomer, 0.5 – 45% silicone oil and 0.1 – 5% microspheres as required by claim 21 or specifically containing 77.25% silicone elastomer, 10% silicone oil and 0.75% microspheres as required by claim 22, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). In the present invention, one would

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have been motivated to optimize the percentage of silicone elastomer, silicone oil and microspheres in order to provide the proper amount of cushioning and elasticity.

As to claims 27 and 28, although Klasson and Stockwell in view of Evans does not explicitly teach that the silicone elastomer layer has the claimed density range of 0.5 g/cm^3 to 1.3 g/cm^3 as required by claim 27, or specifically 0.94 g/cm^3 as required by claim 28, a tensile strength of 0.1 Pa as required by claim 27, or specifically 0.5 Pa as required by claim 28, a durometer reading of 13 – 62 as required by claim 27, or specifically 22 as required by claim 28, 100% modulus of 5kPa to 250kPa as required by claim 27, or specifically 20 kPa as required by claim 28 and compression set of 0 to 30 as required by claim 27, or specifically 8 as required by claim 28, it is reasonable to presume that claimed density range of 0.5 g/cm^3 to 1.3 g/cm^3 as required by claim 27, or specifically 0.94 g/cm^3 as required by claim 28, a tensile strength of 0.1 Pa as required by claim 27, or specifically 0.5 Pa as required by claim 28, a durometer reading of 13 – 62 as required by claim 27, or specifically 22 as required by claim 28, 100% modulus of 5kPa to 250kPa as required by claim 27, or specifically 20 kPa as required by claim 28 and compression set of 0 to 30 as required by claim 27, or specifically 8 as required by claim 28 are inherent to Stockwell. Support for said presumption is found in the use of like materials ([i.e. a cured silicone elastomer layer containing silicone oil) which would result in the claimed property. The burden is upon the Applicant to prove otherwise. *In re Fitzgerald* 205 USPQ 594. In addition, the presently claimed property of density range of 0.5 g/cm^3 to 1.3 g/cm^3 as required by claim 27, or specifically 0.94 g/cm^3 as required by claim 28, a tensile strength of 0.1 Pa as required by claim 27, or specifically 0.5 Pa as required by claim 28, a durometer reading of 13 – 62 as required by claim 27, or specifically 22 as required by claim 28, 100% modulus of 5kPa to

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250kPa as required by claim 27, or specifically 20 kPa as required by claim 28 and compression set of 0 to 30 as required by claim 27, or specifically 8 as required by claim 28 would obviously have been present once the Stockwell product is provided. Note *In re Best*, 195 USPQ at 433, footnote 4 (CCPA 1977). In the present invention, one would have been motivated to have a sleeve with these characteristics to provide the desired functionality.

22. Claims 23 – 26 and 29 – 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klasson et al. (US 4,923,474), Stockwell (US 5,359,735) and Evans et al. (US 4,463,118) in further view of Ogawa et al. (US 5,658,578).

As to claims 23 – 26 and 29 – 30, the features of the patent are set forth above.

However, Klasson and Stockwell in view of Evans fail to disclose the use of one or more skin treatment agents applied to the silicone elastomer.

Ogawa teaches a cosmetic composition for external application to the skin which provides improved effects on the skin such as healing of wounds, prevention of skin roughening and skin improvement (column 1, lines 40 – 46).

Ogawa discloses that the composition can contain Vaseline (column 2, line 35) as required by claims 24 – 26 and 29 - 30, silicone oil (column 2, line 35) as required by claims 29 and 30 and aloe (column 3, line 19) as required by claims 25 – 26 and 29 - 30.

As to claims 24, 26, 29 and 30, Ogawa discloses the claimed invention except for the content of Vaseline of up to 15% or the presence of up to 20% Vaseline and 3% by weight of aloe vera.

As to claims 29 and 30, Ogawa fails to disclose that the silicone elastomer layer comprises by weight 77.25% silicone, 10% silicone oil, 11.9% Vaseline, 0.75% microspheres, and 0.1% aloe vera.

It should be noted that the percent content of silicone, silicone oil, Vaseline, microspheres and aloe vera is a result effective variable. For example, increasing or decreasing the amount of silicone directly affects the flexibility and strength of the composite material. Increasing or decreasing the amount of silicone oil, directly affects the processability of the silicone. Increasing or decreasing the amount of Vaseline or aloe vera, directly affects the moisturizing and healing effect of the composite material. Increasing or decreasing the amount of microspheres, directly affects the cushioning properties of the composite material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to create a silicone elastic material comprising by weight 77.25% silicone, 10% silicone oil, 11.9% Vaseline, 0.75% microspheres, and 0.1% aloe vera, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). In the present invention, one would have optimized the amount of silicone, silicone oil, Vaseline, microspheres and aloe vera, motivated by the desire to obtain a composite material used for skin treatment having increased healing effects, comfort and moisturizing.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add at least one skin sanitizing composition of Ogawa to the sleeve of Klasson and Stockwell in view of Evans motivated by the desire to kill germs, eliminate the possibility of infections and moisturize the stump when supported by a sleeve.

Allowable Subject Matter

23. Claim 6 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

24. The following is a statement of reasons for the indication of allowable subject matter:
The prior art of record does not teach or suggest a composite elastic material useful for prosthetic applications comprising a silicone layer containing microspheres and a knit textile reinforcement matrix embedded in silicone.



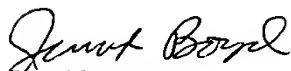
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer A Boyd whose telephone number is 703-305-7082. The examiner can normally be reached on Monday thru Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel Morris can be reached on 703-308-2414. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



Jennifer Boyd
October 31, 2002